



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/178,126	10/23/1998	TIMOTHY STIVLAND	1001.1294101	4007
28075	7590	04/28/2005	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/178,126	STIVLAND ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal brief filed on July 1, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 49-56, 61-64, 67, 69 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510.

Sirhan et al. discloses the invention substantially as claimed. More specifically, Sirhan et al. discloses a first tube (32 and 47) including an inflation lumen (36, see col. 5, lines 56-57) in fluid communication with a dilatation balloon (37), an inside wall surface, and an outside wall surface, said first tube having an orifice (42) in a proximal portion of said first tube; a second tube (33 and layer overlying 47 near orifice 42 in fig. 16) inserted through, and extending distally from said orifice inside said inflation lumen, said second tube having a length, a lumen therethrough, a proximal portion, an inside wall surface and an outside wall surface, see Figure 16; said second tube inside wall surface being formed of a second, lubricous material for a majority of said second tube length, said first tube wall having a layer of a first, flexible material extending for a majority of said first tube length, said first material being different from said second material (column 9, lines 46-53.)

However, Sirhan et al. does not teach a bonding region wherein said second tube outside wall surface is bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces.

Sirhan et al. however teaches that the inner and outer tubular members may be secured together by heat or laser bonding, heat shrinking the outer tube onto the inner tube or other suitable means(col. 3, lines 21-23; see also col. 7, line 59 – col. 8, line 16.) Figure 16 discloses a portion of the second tube (i.e., layer overlying 47 near orifice 42

Art Unit: 1641

in fig. 16) overlaying the first tube (32 and 47). Although, Sirhan et al. does not specifically disclose how this portion of the second tube is bonded to the first tube, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use heat bonding (i.e., re-flow) between the two tube layers because Sirhan et al. teaches that heat bonding is a suitable means to bond inner and outer tubular members together.

As to the following claims, Sirhan et al. discloses the limitations as follows.

As to claim 50, said bonding region is proximate said orifice, see column 5, lines 52-56, and see Figure 6.

As to claim 51, said bonding region includes bonding between said first tube inside surface and said second tube outside surface distal of said orifice, see column 3, lines 17-23.

As to claim 52, said second tube inside and outside wall surfaces are formed of said second material, see column 9, lines 46-53.

As to claim 53, said second tube wall is formed of substantially said second material therethrough, see column 9, lines 46-53.

As to claim 54, said first tube inside surface is formed of said second material proximate said bonding region, see column 9, lines 46-53.

As to claim 55, said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region, see column 9, lines 46-53.

As to claims 61-64, Sirhan et al. disclose that the catheter shaft, including the inner and outer tubular members may be made from polymeric materials such as polyethylene, polyamide, etc and other suitable polymeric materials, see column 9, lines 46-53.

However, Sirhan et al. does not disclose a tie-layer disposed between the inside and outside layers, wherein said intermediate tie-layer is disposed at an angle relative to a tube wall of said first tube.

Fontirroche discloses a tie-layer, comprising Plexar™ for example, may be used to bond together dissimilar outer plastic layers, see column 2, lines 35-38, including plastics that are normally sealingly incompatible with each other (col. 3, lines 9-10). Moreover, Fontirroche discloses that the chemical bonding between two catheter layers can be subsequently heat treated, see column 3, lines 17-20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to bond the plastic layers of the Sirhan et al. catheter by using Plexar because Fontirroche teaches that Plexar provides the advantage of bonding dissimilar plastic catheter layers including plastics that are normally sealingly incompatible with each other.

Moreover, the bonding portion, i.e., the tie-layer portion, in the Sirhan et al. catheter is considered to be disposed between a proximal portion and a distal portion of a tube wall of said first tube, as claimed by Applicant. (Applicant has not specifically defined where the proximal portion and distal portion begins and ends.)

Also, the tie-layer is considered to be disposed at an angle relative to said tube wall. (Applicant has not specifically defined whether the angle is 90 degrees or 180 degrees, for example.)

2. Claims 57, 60, 66, 68, 70, 72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, as applied to claims 56, 65, 69, 71, 73 above, and further in view of Berg et al., 5,792,116.

Sirhan et al. in view of Fontirroche et al. discloses the invention substantially as claimed, see above with respect to claim 56. More specifically, Sirhan discloses that polymeric materials may be used to form the inner or outer tubular members, see column 9, lines 46-53. However, Sirhan et al. in view of Fontirroche et al. does not disclose an outside layer of PEBA.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

3. Claims 58, 59, 65 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, and further in view of Javier, Jr. et al., 6,093,177.

Sirhan et al. in view of Fontirroche et al. disclose the invention substantially as claimed (see above), except for the first tube having an inside surface formed of said second material proximate said bonding region and said inside surface formed of said first material distal of said bonding region.

However, Javier, Jr. et al. discloses that relative flexibility or the inverse stiffness of the various shaft sections of a catheter may be achieved by selecting different materials. "[T]he material used in the intermediate shaft section may be inherently more flexible than a different material used in the proximal or distal shaft sections", see column 2, lines 5-15. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide different materials on different shaft sections of the Sirhan et al. catheter in order to achieve the desired flexibility of the catheter shaft sections as may be necessary for a particular treatment of a patient

4. Claims 60 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view of Javier, Jr. et al., 6,093,177, further in view of Fontirroche et al., 5,538,510, as applied to claim 59, and further in view of Berg et al., 5,792,116.

Although Sirhan in view of Javier and further in view of Fontirroche disclose the invention substantially as claimed, they however do not disclose the first tube being formed of PEBA distal of said tie-layer.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

5. Claims 75-82, 87-90, 93, 95 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, and further in view of Ressemann et al., 5,571,087.

Sirhan et al. discloses the invention substantially as claimed. More specifically Sirhan et al. discloses a first tube (32) including an inflation lumen (36 and proximal portion of 37) in fluid communication with a dilatation balloon (distal portion of 37), an inside wall surface, and an outside wall surface, said first tube having an orifice (42) in a proximal portion of said first tube; a second tube inserted through, and extending distally from said orifice inside said inflation lumen, said second tube having a length, a lumen therethrough, a proximal portion, an inside wall surface and an outside wall surface, see Figure 16; and a bonding region wherein said second tube outside wall surface is

Art Unit: 1641

bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces, see column 3, lines 17-23, and column 7, line 59 – column 8, line 16, said second tube inside wall surface being formed of a second, lubricous material for a majority of said second tube length, said first tube wall having a layer of a first, flexible material extending for a majority of said first tube length, said first material being different from said second material, see column 9, lines 46-53.

However, Sirhan et al. does not disclose a tie-layer disposed between the inside and outside layers, wherein said intermediate tie-layer is disposed at an angle relative to a tube wall of said first tube.

Fontirroche discloses a tie-layer, comprising Plexar™ for example, may be used to bond together dissimilar outer plastic layers, see column 2, lines 35-38. Moreover, Fontirroche discloses that the chemical bonding between two catheter layers can be subsequently heat treated, see column 3, lines 17-20. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to bond the plastic layers of the Sirhan et al. catheter by using Plexar as a tie-layer to bond the plastic layers, as taught by Fontirroche.

Also, Sirhan et al. does not teach a core wire extending distally from the third tube into the first tube.

Ressemann et al. however teaches a catheter (20) having a section (22) being relatively stiff and the distal shaft section (23) being relatively flexible, the configuration of which will tend to bend or buckle in the relatively flexible area as an attempt is made to advance the catheter (2) through a vasculature, the catheter tending to kink at the

Art Unit: 1641

transition section. Ressemann et al. teaches that a core wire (25), see column 7, lines 26-27, in the catheter provides two functions: to provide axial or column strength to the distal shaft section (24); and to prevent kinking of the distal shaft section (24). It would have been obvious to provide a core wire, as taught by Ressemann et al., in the Sirhan et al.-in-view-of-Fontirroche device in order to provide the advantage of axial strength to the distal shaft section, and/or to prevent kinking of the distal shaft section, which may comprise a different material from a proximal section.

As to the limitations in the following claims, Sirhan et al. discloses the limitations as follows. As to claim 76, said bonding region is proximate said orifice, see column 5, lines 52-56, and see Figure 6.

As to claim 77, said bonding region includes bonding between said first tube inside surface and said second tube outside surface distal of said orifice, see column 3, lines 17-23.

As to claim 78, said second tube inside and outside wall surfaces are formed of said second material, see column 9, lines 46-53.

As to claim 79, said second tube wall is formed of substantially said second material therethrough, see column 9, lines 46-53.

As to claim 80, said first tube inside surface is formed of said second material proximate said bonding region, see column 9, lines 46-53.

As to claims 81, 89, said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region, see column 9, lines 46-53.

As to claims 83, 87, 88, 90, the catheter shaft, including the inner and outer tubular members may be made from polymeric materials such as polyethylene, polyamide, etc and other suitable polymeric materials, see column 9, lines 46-53.

The third tube, the first tube being disposed distal of the third tube, is disclosed. (The third tube is considered to be a proximal section of said first tube, or alternatively, a proximal section of said second tube.)

6. Claim 83, 94, 96 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view Fontirroche et al., 5,538,510,, and further in view of Ressemann et al., and further in view of Berg et al., 5,792,116. Sirhan et al., Fontirroche et al., and Ressemann et al. disclose the invention substantially as claimed (see above), except for the outside layer being comprised of PEBA.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

7. Claims 84, 85, 91 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view Fontirroche et al., 5,538,510, in view of

Ressemann et al., and further in view of Javier, Jr. et al., 6,093,177. Sirhan et al., Fontirroche et al., and Ressemann et al. disclose the invention substantially as claimed (see above), except for the first tube having an inside surface formed of said second material proximate said bonding region and said inside surface being formed of said first material distal of said bonding region.

However, Javier, Jr. et al. discloses that relative flexibility or the inverse stiffness of the various shaft sections of a catheter may be achieved by selecting different materials. "[T]he material used in the intermediate shaft section may be inherently more flexible than a different material used in the proximal or distal shaft sections", see column 2, lines 5-15. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide different materials on different shaft sections of the Sirhan et al. catheter in order to achieve the desired flexibility of the catheter shaft sections as may be necessary for a particular treatment of a patient

8. Claims 86, 92 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al, in view of Fontirroche et al., 5,538,510., further in view of Ressemann et al., further in view of Javier, Jr. et al., 6,093,177, and further in view of Berg et al., 5,792,116.

Although Sirhan in view of Fontirroche in view of Ressemann et al. and further in view of Javier, Jr et al. disclose the invention substantially as claimed, they however do not disclose the first tube being formed of PEBA distal of said tie-layer.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection. The first tube is now considered to be at (32 and 47) and the second tube is now considered to be at (33 and layer overlying 47 near orifice 42 in fig. 16).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/25/05